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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,575	02/27/2002	Muraleedharan G. Nair	NP4039.P2	9173

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ALTICOR INC.
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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 05/07/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,575

Applicant(s)

Nair et al.

Examiner

Christopher Tate

Art Unit

1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to a method of alleviating or reducing pain in a mammal in need thereof via providing an effective amount of an elderberry extract which is substantially free of anthocyanidins, classified in class 424, subclass 777, for example.
- II. Claims 12-27, drawn to a method of alleviating or reducing pain in a mammal in need thereof via providing an effective amount of an anthocyanin-containing plant extract, classified in class 424, subclass 737, for example.
- III. Claims 28-35, drawn to a method to reduce the propensity of gastric or intestinal ulceration of an active agent via providing an effective amount of an anthocyanin-containing plant extract, classified in class 424, subclass 725, for example.
- IV. Claims 36-41, drawn to a method to reduce gastric or intestinal ulceration in a mammal via providing an effective amount of an anthocyanin, classified in class 514, subclass 183, for example.
- V. Claims 42-43, drawn to a dietary supplement comprising at least one pain-reducing agent and an effective amount of elderberry, classified in class 424, subclass 732, for example.

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- VI. Claim 44, drawn to a method for inhibiting cyclooxygenase or prostaglandin H synthase enzymes via providing an anthocyanin, classified in class 435, subclass 183, for example.
- VII. Claim 45, drawn to a food supplement having anti-inflammatory properties comprising two or more anthocyanin-enriched plant extracts selected from numerous distinct plants, classified in class 426, subclass 615, for example.
- VIII. Claim 46, drawn to a food supplement having anti-inflammatory properties comprising an undefined anthocyanin-containing extract, classified in class 424, subclass 648, for example.
- IX. Claims 47-52, drawn to a dietary supplement comprising at least one joint health agent (such as glucosamine) and an anthocyanin-enriched plant extract, classified in class 514, subclass 55, for example.
- X. Claims 53-54, drawn to a dietary supplement comprising at least one prostate health agent (such as saw palmetto) and an anthocyanin-enriched plant extract, classified in class 424, subclass 727, for example.
- XI. Claims 55-56, drawn to a dietary supplement comprising at least one GLA agent (such as evening primrose), classified in class 424, subclass 725, for example.

The inventions I-XI are distinct, each from the other because of the following reasons:

Inventions V, VII, VIII, IX, X, XI (distinct products) and I-IV & VI (distinct methods), are related as products and processes of use. The inventions can be shown to be distinct if either

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or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, there are numerous methods of bringing about the instantly claimed, distinct therapeutic effects (e.g., alleviating/reducing pain, reducing the propensity of gastric/ intestinal ulceration of an active agent, inhibiting cyclooxygenase or prostaglandin H synthase enzymes) which do not require any or of the active herbal agents instantly claimed, such as via the use of various conventional over-the-counter and/or prescription medications.

The products of Groups V, VII, VIII, IX, X, and XI are distinct, each from the other because, as evidenced by the claims themselves, they are composed of different combinations of essential active ingredients therein (including other active ingredients which provide different and distinct functional effects - e.g., for anti-inflammatory joint health, for prostate health, or for providing a woman's well being during her menstrual cycle), including that some comprise one of various distinct plant extracts while others comprise one of various distinct anthocyanin compounds which are not necessarily required of the other groups. The remaining groups are directed to different inventions which are not connected in design, operation, or effect. These methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone. Thus, the inventions above are distinct, each from the other. Further, they have acquired a

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separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. In addition, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and the search required for each Group is not necessarily required for the other Groups, restriction for examination purposes as indicated is proper.

In addition, this application contains claims directed to the following patentably distinct species of the claimed invention:

- A. The various distinct anthocyanin-containing plants instantly claimed - e.g., in claims 13-17, 45, and 49-50.
- B. The various distinct anthocyanin compounds instantly claimed - e.g., in claims 23-27, 39, and 44.
- C. The various distinct joint health agents instantly claimed - e.g., in claim 48.
- D. The various distinct prostate health agents instantly claimed - e.g., in claim 54.
- E. The various distinct GLA agents instantly claimed - e.g., in claim 56.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable (i.e., applicant is required to elected a particular element, or a particular combination of two or more elements, from species A-E above, insofar as they relate to a particular elected invention from among Groups I-XI above, in response to this Office action).

Currently, claims 1, 12, 20, 23, 28, 36, 42, 44-47, 53, and 55 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.



Christopher R. Tate
Primary Examiner, Group 1654